REMARKS

The Final Office Action mailed December 13, 2007, has been received and reviewed. Claims 1, 2, and 4 through 35 are currently pending in the application. Claims 1, 2, 4 through 14, 16 through 28, and 30 through 35 stand rejected. Claim 25 is objected to due to informalities in the claim language. Appropriate correction has been made. Applicants propose to amend claim 25 and respectfully request reconsideration of the application as proposed to be amended herein.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 6,130,200 to Brodbeck et al.

Claims 1, 2, 4 through 14, 16 through 28, and 30 through 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Brodbeck et al.(U.S. Patent No. 6,130,200) in view of Yamagata et al. (U.S. Patent No. 5,628,993) and Ayer et al. (U.S. Patent No. 6,096,339). Applicants respectfully traverse this rejection, as hereinafter set forth.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) **must teach or suggest all the claim limitations**. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Additionally, there must be "a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Finally, to establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Furthermore, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006); MPEP § 2144. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742; *DyStar*, 464 F.3d at 1367.

The 35 U.S.C. § 103(a) obviousness rejections of claims 1-14, 16-28, and 30-35 are improper because the cited references do not teach all of the claim limitations.

Claim 1 currently recites a composition comprising a carrier and particulates comprising a compressed mixture of an active agent and an agent exhibiting a characteristic of low solubility in water, wherein the hydrophobic agent is selected from the group consisting of pharmaceutically acceptable oil, fats, fatty acids, fatty acid esters, waxes and mixtures an derivatives thereof that exhibit the hydrophobic characteristic, the particulates being dispersed within the carrier.

As a preliminary matter, Brodbeck is relied upon as prior art under 35 U.S.C. § 102(e) because the inventive entity differs from that of the instant application. (Final Office Action at page 4). However, Brodbeck does not constitute prior art under 35 U.S.C. § 102(e) because the subject matter and the claimed invention were, at the time the claimed invention was made, subject to an obligation of assignment to Alza Corporation. Since both Brodbeck and the present application, which includes a filed assignment (recorded on June 8, 2000, at Reel 010908, Frame 0900), are both assigned to Alza Corporation and because such obligation to assign existed at the time the invention was made, Brodbeck does not constitute as prior art under Seciton 102(e) or Section 103.

Notwithstanding the fact that Brodbeck does not constitute prior art, Applicants respectfully disagree with the Examiner's interpretation of Brodbeck. Brodbeck is relied upon as teaching a sustained-release pharmaceutical composition comprising particles of spray-dried, lyophilized human growth hormone and zinc acetate suspended in a gel of poly-(D,L-lactide-co-glycolide) (PLGA, a biocompatible gel carrier) and benzyl benzoate. (Office Action at pg. 5).

Brodbeck, as described in the Description of Related Art section of the application (page 4, lines 10-21), is drawn to a system based on polymer/solvent compositions that form a gel and control the rate of ingress of water into the bulk polymeric system. The Examiner appears to argue that Brodbeck discloses the compressed particles of the present invention because the lyophilized drug particles disclosed therein are "compressed" in the same sense as the particulates used in the present invention, due to their size (2-100 micron particles). Thus, the Examiner is interpreting the term "compressed" in the present claims as meaning merely "small". Applicants respectfully submit that this interpretation is incorrect.

The particulates used in the present invention are "compressed" in the sense that they have been subjected to compression, i.e. put under high pressure, for example by tableting, roller compaction, or extrusion (see, for example, page 12, line 12 to page 13, line 20). Compression is accomplished at "pressures high enough to compact the material and produced a compacted body". The compacted body is then "milled or ground to form particulates..." (Id.). Compression reduces the ratio of surface area to mass of the particulates, i.e. increases their density, which reduces the burst of beneficial agent from implantable systems, and clearly does not determine their particle size, contrary to the assertions of the Examiner. The particle size of the particulates is instead determined by the milling or grinding to which the compressed material is subsequently subjected, which step is unconnected to the compression step. Accordingly, the term "compressed" as used in the present claims clearly refers to particulates which have been formed from material which has been subjected to pressure, and is not merely used as an equivalent term to "small".

As discussed in the present application, compression reduces the ratio of surface area to mass of the particulates, and reduces the rate of dissolution, dispersion or diffusion of the beneficial agent when exposed to bodily fluids in an environment of use. The composition of the present invention can thus reduce the burst of beneficial agent, and increase the loading capacity of the carrier, so that delivery of the beneficial agent may be extended over a prolonged period of time. This allows for fewer doses where administration of beneficial agent must be carried out over a prolonged period of time. The technical problem of how to increase the loading capacity of the carrier whilst reducing burst of beneficial agent is simply not addressed by the cited prior art documents. A skilled person reading the cited prior art documents would not be obviously lead to the present invention, and we submit that the present invention is thus patentable over the disclosure of these documents.

In the Final Office Action, Brodbeck is relied upon as teaching "sprayin at 5mg/ml aqueous solution of human growth hormone (HGH) onto a solid surface, then allowing it to dry into solid particles . . . [t]hese particles yielded by the drying method of Brodbeck are 'compressed' since the water has evaporated from the composition prior to the drying, yielding a composition whose bulk density is greater than it was prior to the drying." (Final Office Action at page 7). As acknowledged by the Examiner, the definition of "compressed" and compressed

particulates" means that compression or compaction has occurred. The reliance on Brodbeck, which is limited to one example where hGH particles are dried, does not teach or suggest compaction or compression of particles. The mere drying of the particles to remove water does not, by necessity, yield "compressed" particles, as suggested by the Examiner. There is no such description in Brodbeck.

Thus, Brodbeck does not disclose, teach or suggest a composition which comprises particulates which have been compressed, as described above. Indeed, there is no mention or suggestion whatsoever in Brodbeck to the use of compressed particulates, per the present invention.

As acknowledged by the Examiner, Brodbeck does not teach or suggest hydrophobic agent is selected from the group consisting of pharmaceutically acceptable oil, fats, fatty acids, fatty acid esters, waxes and mixtures an derivatives thereof that exhibit the hydrophobic characteristic. To overcome this particular deficiency, the Examiner relies on Yamagata as teaching a composition comprising powdered particles of interferon-α dispersed in a matrix of tetraglycerol dipalmitate or tetraglycerol. Ayer is also relied upon as teaching particles comprising active agents that are included in compositions that may be made by spray-drying or crushing. (Office action at pg. 6). However, Yamagata and Ayer do not overcome the deficiencies of Brodbeck. Specifically, Yamagata and Ayer do not teach or suggest a compressed mixture of an active agent and an agent exhibiting a characteristic of low solubility in water.

In view of the foregoing amendments and arguments, Applicants respectfully request withdrawal of the present rejection to claims 1-14, 16-28, and 30-35.

Claim Objections

Claim 25 is objected to due to informalities in the claim language. Appropriate correction has been made.

ENTRY OF AMENDMENTS

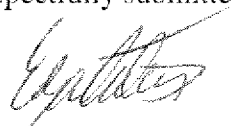
The proposed amendments to claim 25 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new

matter to the application. Further, the amendments do not raise new issues or require a further search. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested upon filing of a Notice of Appeal herein.

CONCLUSION

Claims 1, 2, 4-14, 16-28, and 30-35 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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